UNITED STATES DISTRICT COURT
DISTRICT OF NEBRASKA

Stephanie Ideus,

Civil File: 4:16-cv-03086-JMG-CRZ

Plaintiff,

vs.

Teva Pharmaceuticals USA, Inc., and Teva Women's Health, Inc.,

Defendants.

REPLY BRIEF OF DEFENDANT TEVA WOMEN'S HEALTH, INC. IN SUPPORT OF OPPOSITION TO PLAINTIFF'S MOTION TO COMPEL A FULL AND COMPLETE RESPONSE TO DOCUMENT REQUESTS 36 AND 38

Now comes Defendant, Teva Women's Health, Inc. ("TWH") and replies to Plaintiff's Brief in Response to Defendant Teva Women's Health, Inc.'s Brief on Burdensomeness of Document Requests 36 and 38 ("Response") (Filing # 47).[1]

I. PLAINTIFF CONCEDES THE DOCUMENTS AT ISSUE ARE NOT RELEVANT TO HER FAILURE TO WARN CLAIM

In its brief opposing plaintiff's motion to compel (Filing # 42) ("TWH Opposing Brief"), TWH showed that plaintiff did not argue and could not show that the complaint investigation files at issue in this motion were relevant to her failure to warn claim. TWH Opposing Brief, pp. 7-9. In her Response, Plaintiff conceded that point. (Response, p. 6).

[1] In her Response, plaintiff states she is unsure why only TWH has submitted a brief. The Discovery Dispute Chart supplied by the parties to the Court (Filing # 40) specifically notes the "responding party is: Defendant Teva Women's Health, Inc." TWH is the entity that manufactures the ParaGard® T380A Intrauterine Copper Contraceptive, is the entity that produced documents, including complaint file documents, to plaintiff previously, and, as indicated in the Opposition and Declaration of TWH employee Thomas Mehs (Filing ## 42 and 43), he is the person who would have to locate, retrieve, and review the additional complaint file documents at issue in this motion.

II. DISPROPORTIONAL DISCOVERY AND UNDUE BURDEN

TWH also demonstrated that the burden imposed on TWH by an Order requiring production of additional complaint investigation files beyond those already produced (i.e., complaint investigation files from lots other than those from which plaintiff's ParaGard came) is substantial and disproportionate to the needs of the case. TWH supplied detailed factual evidence showing that the burden of locating, retrieving, and reviewing documents to identify those responsive to plaintiff's request is undue and unreasonable in light of the non-existent explanation for how the requested documents are relevant to the thus far undescribed design or manufacturing defect she contends. TWH also outlined the disruption such an Order would cause.

In her Response, plaintiff contends that TWH's evidence only details the usual burdens, inconveniences, and costs that are associated with discovery practice in every case. Response, pp. 5-6. Plaintiff supplied no factual support for those contentions. The 2015 Advisory Committee notes that "[t]he burden or expense of proposed discovery should be determined in a realistic way." Rule 26, Advisory Comm. Notes, 2015 Amends, ¶ 16. And, "[c]ourts should examine each case individually to determine the weight and importance of the proportionality factors." *Applied Underwriters, Inc. v. Top's Personnel, Inc.*, 2017 WL 1214413, *2 (D. Neb. March 31, 2017) (Zwart, J). All that is before the Court is the evidence TWH submitted which remains unrebutted; plaintiff's speculative argument does not assist in the proportionality determination.

In addition, the cases she relies upon are unhelpful to the Court's analysis. Most of the cases relate to motions to stay discovery pending a motion to dismiss or a motion to bifurcate damages from liability and stay damages discovery. In the *TSM Associates* case cited by

plaintiff (Response, p. 6), defendant did not even argue that discovery in the case would be overly burdensome. *TSM Associates, LLC v. Tractor Supply Co.*, 2008 WL 2404818 (N.D. Ok. June 11, 2008), * 1. None of these cases present a fact pattern close to that before the Court. All but one were decided before the disproportionality standard was put in place to help curb the burdens imposed upon defendants by the kind of breezy and self-serving reference to "usual burden" by the courts in the cases cited and made by plaintiff. TWH has demonstrated this is not the part of the usual burden to Mr. Mehs. As reflected in the Declaration of Thomas E. Mehs (Filing # 43), his time is fully occupied with non-litigation matters and he has estimated 85 hours on his end alone would be necessary to comply with plaintiff's burdensome requests. Those hours are entirely additive to his usual work responsibilities. TWH is confident that plaintiff (and her counsel) would not be so cavalier if they were told they had to divert the equivalent of over two weeks from what they normally do.

Also off base is plaintiff's assertion that TWH's record-keeping is to blame for the burden arising from plaintiff's request. The complaint file system is set up for specific business and regulatory purposes. There was no obligation to set up those systems and records anticipating that at some point a plaintiff in a lawsuit may make the request plaintiff makes here. As pointed out in TWH's Opposing Brief, those business and regulatory purposes go beyond ParaGard and other TWH products. The fact that there is no reason in fulfilling those business and regulatory purposes to separately categorize in the systems and records a known event that has appeared for a long time in the FDA-approved labeling (embedded arm broken upon removal) does not mean there is some deficiency in the systems or records for which TWH should be penalized, as plaintiff suggests.

Moreover, while plaintiff concedes it is her burden "to explain the ways in which the

underlying information bears on the issues as that party understands them" (Response, p. 3), she not provided that explanation for the complaint files from other lots.

As plaintiff asks for additional documents and seeks to impose the associated burdens on TWH, it is reasonable and proportional to ask whether plaintiff has looked thoroughly at the documents she has received from TWH. Based on the statements in her response, the answer is, apparently not. Plaintiff alleges TWH produced "only the New Drug Application, the MAUDE Reports, and some other miscellaneous documents." (Response, p. 5.) The New Drug Application consists of not only the original application, but also correspondence with FDA about the NDA and supplements to the NDA, and Annual Reports submitted to FDA pursuant to 21 CFR §314.81, addressing manufacturing and labeling matters, among others. The "other miscellaneous documents" include the batch record describing the manufacturing and quality standards and process for plaintiff's ParaGard and all other units in the same lot. The documents include the Drug Master File, which contains the design specification and relevant procedures. Plaintiff's assertion that the documents include "MAUDE Reports" reflects a fundamental misunderstanding of the documents and the fact that ParaGard is an FDA-approved prescription drug instead of a medical device. MAUDE is FDA's reporting system for medical devices.

III. COMPLAINT INVESTIGATION FILES ARE NOT RELEVANT TO PLAINTIFF'S DESIGN DEFECT ALLEGATIONS

TWH demonstrated that the complaint investigation files and the federal regulations governing them, by their very nature, are not part of the product design process and are not relevant to design. TWH Opposing Brief, pp. 12-13. Plaintiff has not disputed that point and cannot. Instead, plaintiff completely ignores the point and argues she is entitled to see what TWH has concluded about the causes of breakage and whether it was from a "design issue."

Response, p. 8. Ignoring the point does not make the files part of the design process or make them relevant.

Plaintiff cannot meet her threshold burden of showing how production of these additional complaint investigation files can relate to a design defect claim, even *if* plaintiff had plead it with specificity. Thus, with regard to her purported design defect claim, requiring production of the additional documents confers no benefit upon plaintiff.

IV. PLAINTIFF'S BOILERPLATE, NON-SPECIFIC ALLEGATIONS DO NOT ENTITLE HER TO BROAD, UNREASONABLE, AND BURDENSOME DISCOVERY

While conceding that the complaint files have nothing to do with her failure to warn claim, plaintiff devotes approximately two pages of her response to specifically describing that claim. That her failure to warn assertions ignores fundamental facts and precepts of law is for another day. The significance for purposes of plaintiff's motion to compel is that she is able to explain her failure to warn claim. Conversely, she is not able to articulate her design defect claim.

That is significant because disproportionality requires plaintiff to come forward with a specific explanation of how the discovery is proportional to the needs of the case and the importance of the discovery in resolving the issues. In order for that standard to have any meaning, that explanation must go beyond the unadorned contention that "I am making a claim." Rule 26, Advisory Committee Notes, 2015 Amends. ¶ 11. Given yet another chance to explain what that claim, design or manufacturing, is, plaintiff again provides none. Rather, she simply says the complaint files may lead to the discovery of admissible evidence, a standard that no longer appears in Rule 26, and does not apply to this case. Indeed, a primary purpose of the substitution of the proportionality standard for the "may lead to" criteria was the unwieldy burdens placed upon parties (i.e., defendants like TWH in product liability cases) by that

amorphous criterion.

Plaintiff also broadly asserts she is entitled to know the results of investigation of complaints from other lots, but she never describes how those results are relevant to either a design defect or manufacturing defect claim. Among the over 8500 pages of documents TWH has produced to her, plaintiff has the design and manufacturing specifications in effect for her ParaGard unit, and the batch record documenting how her ParaGard and all the other ParaGards in her lot were made. Yet, she has not described what she contends is the defect in the design. Under Nebraska law, plaintiff is required to demonstrate how *her* particular ParaGard deviated from the manufacturing specifications. She has not identified any alleged shortcoming in the manufacturing process. And notwithstanding the fact that she has complaint investigation files from her lot, she has not asserted, and certainly never explains, what it was that she found in those files supporting her claims that she now seeks to discover in complaint files from other lots. Under the circumstances before the Court, there is no logical reason to permit the expensive, burdensome, and disproportionate discovery requested by plaintiff.

Further, plaintiff argues she "is attempting to gather proof of what caused the breakage, including Defendants' internal analysis of similar breakage claims and complaints." (Response, p. 9). There is no mystery. As identified in the ParaGard labeling, and has been known in the relevant health care professional community, when ParaGard arm is embedded in uterine myometrial tissue (as was plaintiff's) an attempted removal of that ParaGard by pulling on the strings may result in breakage of the arm Moreover, this concession illustrates that plaintiff is, indeed using the mere occurrence of an event (breakage) as proof of a defect and as a hook to conduct a fishing expedition. Under Nebraska law, however, the mere occurrence of an event cannot be used to prove a defect. *Uribe v. Sofamor,* S.N.C., 1999 WL 1129703, *4 (D. Neb.

Aug. 6, 1999), citing *Delgado v. Inryco*, Inc., 433 N.W.2d 179, 184-185 (Neb. 1988).

Plaintiff's arguments relative to the pleading deficiencies pointed out by TWH also miss the mark. TWH argued that plaintiff nowhere alleged in her Amended Complaint (Filing # 21) the nature of her manufacturing or design defect claims or how these purported defects caused her alleged injury. In her Response, plaintiff contends that she did make a design defect claim and, at pages 2-3 of her Response, provides the text thereof. But as discussed in TWH's Opposing Brief (at pp. 11-13) and the recently filed motion for judgment on the pleadings (Filing # 45), these boilerplate allegations do not permit broad-ranging discovery and are insufficient to state a claim. They do not allege the nature of any purported defect with any factual specificity and alleged expansive theories of liability do not necessarily justify expansive discovery. *Hajek v. Kumho Tire Co., Inc*., 2010 WL 503044 at *5 (D. Neb. Feb. 2, 2010) (Zwart, J.) citing *In re Cooper Tire & Rubber Co*., 568 F.3d 1180, 1193 *10th Cir. 2009)). This is not, as plaintiff argues, a dispositive argument as it relates to the within motion (Response, p. 9), but demonstrates that plaintiff cannot show that requested documents are relevant to any specific factual claim she has made, because she has made none.

The *Shelby* case upon which plaintiff relies is instructive. There, plaintiff alleged she suffered a pattern of sexual harassment, discrimination and retaliation in violation of various federal and state statutes. *Shelby v. City of Omaha*, 2016 WL 6781216 (D. Neb. Nov. 26, 2016). But plaintiff also specifically alleged facts supporting her claims. *Id.* at *1. Utilizing those specific factual allegations, the court was able to determine that the discovery she sought was relevant to the specific factual claims she plead. *Id.* at *2 ("Shelby has met her burden of demonstrating the relevance of the discovery sought. The requests incorporate the investigation files, which include information bearing on her claims about her underlying treatment and the

process following her complaints.") Here, however, plaintiff has only pled boilerplate and no supporting facts.

Plaintiff next contends that her portion of the Rule 26(f) Report specified a design defect claim. Rule 26(f) is entitled "Conference of the Parties; Planning for Discovery." Under Rule 26, the discovery plan must state the parties' views and proposals on "the subjects on which discovery may be needed." 26(f)(3)(B). In addition, the parties are to "consider the nature and basis of their claims and defenses." Rule 26(f)(2). Plaintiff did neither, demonstrating that her case really is a failure to warn case and that design defect claims are really an afterthought, raised for the first time in connection with this discovery dispute.

The language plaintiff cites (Response, p. 3), is, as detailed by TWH earlier, is invariably coupled with the reference to defendants' purported failure to warn and plaintiff concedes the complaint investigation files are not relevant to her failure to warn claims. Nowhere does plaintiff identify any defect in the ParaGard design or any facts that her ParaGard was not manufactured in accordance with the product specifications, both of which are her burden.

The documents at issue in this motion are not relevant to any claims plaintiff is pursuing. In addition, an Order requiring their production would be unduly burdensome and disruptive to TWH's normal business, and would not confer any benefit upon plaintiff.

WHEREFORE, Teva Women's Health respectfully requests an Order denying plaintiff's motion to compel an additional response to document request 36 and 38[2].

[2] As noted in TWH's Opposing Brief, TWH no longer believes there is a dispute as to Request number 38 as TWH has represented it will, subject to and without waiving any of its previously asserted objections, provide a second supplemental response to plaintiff's Request No. 38 indicating there have been no "recalls," as Teva Women's Health understands that term, of ParaGard® units from lots manufactured after November 9, 2005, because of embedded arms of ParaGard® units being broken upon removal.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing Reply Brief of Defendant Teva Women's Health, Inc. In Support of Opposition to Plaintiff's Motion to Compel a Full and Complete Response to Document Requests 36 and 38 has been served electronically this 17th day of July, 2017, upon attorneys who have completed ECF registration as required by the Court, including:

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